

REMARKS

Claims 1-13, 15-19, 21, 23, and 24 are pending in the application and have been examined. Claims 1-13, 15-19, 21, 23, and 24 stand rejected. Claims 1, 15, 16, and 21 have been amended. Reconsideration and allowance of Claims 1-13, 15-19, 21, 23, and 24 in view of the following remarks is respectfully requested.

The Rejection of Claims 1-13, 15-19, 21, 23, and 24 Under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 1-13, 15-19, 21, 23, and 24 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner has taken the view that the phrase "a maintenance medium comprising one or more agents for adjusting the osmolality of the medium to a desired range" is not supported by the specification as filed. While not acquiescing to the Examiner's position, but in order to facilitate prosecution, Claim 1 has been amended to replace the phrase "and one or more agents for adjusting the osmolality of the medium to a desired range" with the phrase "wherein the osmolality of the maintenance medium is from 180mM/Kg to 400mM/Kg." Support for this amendment is found throughout the specification as filed, for example, at page 9, lines 5-8.

Accordingly, removal of this ground of rejection is respectfully requested.

The Rejection of Claims 1-13, 15-18, 21, 23, and 24 Under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 1-13, 15-18, 21, 23, and 24 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement.

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While not acquiescing to the Examiner's position, but in order to facilitate prosecution, Claim 1 (from which Claims 2-13, 15-18, 21, 23, and 24 depend) has been amended to recite that the method is for producing a synchronized population of pine embryogenic tissue. Support for this amendment is found throughout the specification as filed, for example, at page 4, lines 7-10, page 12, line 24, to page 17, line 32, and page 18, line 1, to page 19, line 31.

The Examiner has taken the view that the specification does not provide enablement support for practicing the method on embryogenic tissue from any conifer species. Applicants disagree with the Examiner's conclusions for at least the following reasons. As noted above, Claim 1 has been amended to replace "conifer" with "pine." As discussed below, the claimed invention as amended is enabled by the specification as filed in view of the knowledge of one skilled in the art at the time of filing.

Moreover, it is submitted that the Examiner has failed to establish a *prima facie* case of non-enablement. As stated in the M.P.E.P. §2164.04, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. However, the Examiner has not presented sound scientific reasoning and objective evidence to support her position of non-enablement.

The Examiner has not provided adequate reasons to establish that a person skilled in the art could not use the members of the genus *Pinus* (pine) recited in amended Claim 1, as compared to Loblolly Pine, without undue experimentation. The Examiner relies on Hansen et al., "Recent advances in the transformation of plants," *Trends in Plant Science Reviews* 4(6):226-231, June 1999, as an example of the state of the art teaching that plant transformation remains an unpredictable art because of the unique culture conditions required for each crop species. However, it is noted that the teachings of Hansen et al. relied upon by the Examiner are directed to plant genetic transformation, which is not relevant to the methods of the

claimed invention. In particular, the teachings of Hansen et al. relied upon by the Examiner are directed to methods that facilitate the genetic transformation of plants via the uptake of DNA by protoplasts following enzymatic or chemical treatments, the delivery of microprojectiles coated with DNA into cells (biolistics), or by Agrobacterium-mediated transfer of DNA vectors into wounded cells or tissues. In contrast to the teachings of Hansen et al., the present invention is directed to culturing pine somatic embryos and does not require the step of genetic transformation. In fact, with regard to culturing embryogenic tissues, which is relevant to the claimed invention, the teachings of Hansen et al. actually support applicants' position that the claimed method is enabled with the statement "[e]mbryogenic tissues are, in general, very prolific." (See Hansen et al. at page 227, first column.)

Contrary to the Examiner's assertion, it is submitted that the claimed invention is enabled by the specification as filed in view of the knowledge of one skilled in the art at the time of filing. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in a patent coupled with information known in the art without undue experimentation.

The invention provides methods for producing a synchronized population of pine somatic embryos by cultivating pre-cotyledonary pine embryogenic cells in or on a synchronization medium that comprises an absorbent composition and at least one synchronization agent selected from the group consisting of abscisic acid and a gibberellin. As stated in the specification, the methods of the invention are applicable to any member of the genus *Pinus*, such as Loblolly Pine (*Pinus taeda*). Specification at page 4, lines 7-10. Working Example 2 demonstrates that pre-treating Loblolly Pine embryogenic cell cultures in a synchronization medium containing activated charcoal and at least one of abscisic acid and a gibberellin, as claimed, was effective to

produce a synchronized population of Loblolly pine somatic embryos. Specification at page 18, line 1, to page 19, line 31.

As stated in the M.P.E.P. § 2164.02:

for a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.

As would be known by those of skill in the art at the time of filing, a reasonable correlation exists between the culturing of Loblolly Pine somatic embryos and somatic embryos from other pine species. For example, attached as Exhibit A, and cited in a Supplemental Information Disclosure submitted herewith, is a journal article by R. Nagmani et al., entitled "Anatomical Comparison of Somatic and Zygotic Embryogeny in Conifers," in S.M. Jain et al. (eds.), Vol. 1, *Somatic Embryogenesis in Woody Plants*, Series: *Forestry Sciences*, Vol. 44, 1995, pp. 23-48. As disclosed in Exhibit A, zygotic and somatic embryos of conifers, which are members of the genus *Pinus*, are anatomically similar and recognized as having similar embryogenic potentials in culture media. For example, as described on page 26, lines 7-9, of Exhibit A, embryo development in the family Pinaceae follows two different pathways after the precotyledonary stage of embryo development: either the cleavage type pathway represented by *Pinus* (Pines), or the non-cleavage type pathway represented by *Picea* (Spruce). FIGURE 11 on page 45 of Exhibit A provides a diagram summarizing the possible routes of *in vitro* origins of somatic embryos in the family Pinaceae, both from primary explants and from embryogenic callus or protoplast cultures. Exhibit A then concludes "[t]he embryogenic potential of an explant was observed to be genus specific. For example, in *Picea* and *Larix*, all types of primary

explants produced embryogenic tissue, whereas, in *Pinus*, the embryogenic tissue or somatic embryos mostly originated from precotyledonary embryos between stages 9-11." (See Exhibit A, page 44, paragraphs 5 and 6, and FIGURE 11 on page 45.)

In view of the foregoing, it is demonstrated that zygotic and somatic pine embryos are anatomically similar and recognized as having similar embryogenic potentials in culture media. Therefore the methods recited in Claim 1 would be recognized by one skilled in the art to be applicable to all members of the genus *Pinus*, in a manner similar to that demonstrated for Loblolly Pine in the working example provided in the instant specification, without requiring undue experimentation.

Therefore, it is demonstrated that the claimed invention as amended is enabled by the guidance in the specification in view of the state of the art at the time of filing. Removal of this ground of rejection is respectfully requested.

The Rejection of Claims 1-13, 15-19, 21, 23, and 24 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-13, 15-19, 21, 23, and 24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner has taken the view that the term "desired range" in the phrase "adjusting the osmolality to a desired range," as recited in Claim 1 is not clear. As noted above, Claim 1 has been amended to delete the phrase "adjusting the osmolality to a desired range." Therefore, removal of this ground of rejection is respectfully requested.

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CONCLUSION

In view of the foregoing remarks, applicants respectfully submit that Claims 1-13, 15-19, 21, 23, and 24 are in condition for allowance. If the Examiner has any questions, she is invited to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Tineka J. Quinton". The signature is fluid and cursive, with a large, stylized "Q" at the end.

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